

Evaluating effects of animal-assisted therapy on pediatric dental care patients

A pilot clinical trial

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Supplemental material is available online.

ABSTRACT

Background. An estimated 6% through 22% of children have dental anxiety, which can contribute to disruptive behavior and oral health care avoidance. Evidence from medical settings indicate reductions in pain and stress after therapy dog implementation. To identify a low-risk, nonpharmacologic approach for anxiety and pain management in dentistry, a pilot prospective clinical trial was conducted to determine best practices for evaluating the efficacy of animal-assisted therapy (AAT).

Methods. The effects of AAT on pediatric patients were measured through physiological, objective measures (ie, heart rate, salivary cortisol and α -amylase, and video coding) and validated self-reported scales of anxiety, fear, and pain, during an invasive dental procedure. Children aged 7 through 14 years were consecutively enrolled into an AAT ($n = 18$) or control ($n = 21$) group. Participants underwent an operative or surgical (eg, extraction) dental procedure. Descriptive and bivariate statistics were used.

Results. Participants in the AAT group reported significantly less postoperative pain than those in the control group ($P = .001$). The heart rates of AAT participants dropped after key events and had less variation than control participants. Objective video coding revealed that AAT participants had significantly longer durations of relaxed lower bodies than control participants ($P = .204$). No differences were seen in salivary cortisol and α -amylase. These physiological and self-report measures are feasible for use in future studies.

Conclusions. AAT may be an effective therapy for alleviating anxiety and pain in pediatric dental patients and warrants additional study using both objective physiological end points and subjective self-report measures.

Practical Implications. Pending further research, canine therapy may be a valuable addition to dental clinics for anxiety and pain management. This clinical trial was registered at ClinicalTrials.gov. The registration number is NCT04708028.

Key Words. Dental anxiety; pediatric dentistry; animal therapy.

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Dental anxiety (DA) is an emotional state of apprehension or a reaction to feeling threatened in a dental setting, manifesting as disruptive behavior and distress.¹ DA is linked to avoidance and increased pain response during dental procedures.²⁻⁴ Avoidant behavior ultimately can increase risk of developing infection and experiencing tooth loss and emergency visits.⁵ The global prevalence of DA in pediatric patients aged 3 through 18 years is 23.9%,⁶ and 16.4% of surveyed adults have DA, with 50.9% reporting anxiety onset in childhood due to early traumatic dental experiences.^{7,8}

Enhancing children's treatment experience and preventing lasting fears of dentistry necessitate the application of behavioral management and anxiety-control techniques.⁷ The American

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ABBREVIATION KEY

AAT:	Animal-assisted therapy.
CFSS-DS:	Children's Fear Survey Schedule-Dental Subscale.
DA:	Dental anxiety.
H1:	After participant's calming period, but before the intervention, not concurrent with saliva collection Salivette swab (Sarstedt Inc) placement.
H2:	During intervention (AAT, control).
H3:	Immediately after intervention (AAT, control).
H4:	Immediately after movement to the clinical treatment room.
H5:	During first injection.
H6:	Immediately after first injection.
H7:	Placement of first isolation or mouth prop.
H8:	Beginning procedure with handpiece or forceps into mouth.
H9:	During procedure (10 minutes into the procedure).
H10:	After procedure (removal of mouth prop, patient is seated upright).
HR:	Heart rate.
MCDAS:	Modified Child Dental Anxiety Scale.
S1:	Baseline at start of study visit.
S2:	Eight minutes after intervention (AAT or control).
S3:	Eight minutes into the dental procedure.
S4:	Eight minutes after completion of the procedure at the end of the study visit.
WBS:	Wong-Baker FACES Pain Rating Scale.

Academy of Pediatric Dentistry outlined developmentally appropriate, evidence-based practices for managing pediatric DA, including use of basic and advanced behavior guidance techniques and nonpharmacologic and pharmacologic treatments.⁸ Rare but substantial risks are associated with moderate to deep sedation (eg, cardiovascular instability and impaired airway reflexes and patency), leading to occasional caregiver resistance.^{8,9} General anesthesia for DA is safe but costly for the patient and the health care system, and expenses continue to increase.¹⁰ A low-cost, low-risk alternative to sedation is needed for patients who are anxious.

Animal-assisted therapy (AAT) is a promising nonpharmacologic intervention that uses a well-trained therapy animal to achieve treatment goals.¹¹ Dogs can sense elevated stress hormones and respond accordingly.¹² Data regarding AAT's positive effects are encouraging and abundant in medicine, with brief AAT interventions decreasing stress hormones and increasing endorphins in adult patients and even health care personnel.^{5,13}

Although implementation of AAT in dentistry is in its early stages, initial data are promising.¹⁴⁻¹⁶ Among children who verbalized distress, a therapy dog decreased their physiological arousal while waiting for their dentist.¹⁴ After a randomized trial at a pediatric dental office, researchers reported a 15-minute interaction with a therapy dog reduced subjective stress in children aged 4 through 11 years.¹⁶ Acceptability of AAT has also been surveyed in pediatrics and orthodontics; 90% of caregivers indicated acceptability of a therapy dog in pediatric dental settings and 68% expressed a desire for a dog to be part of their child's treatment.¹⁵ Orthodontic patients and their parents or guardians indicated broad interest in therapy dogs, with few to no safety concerns.¹⁷

Dental AAT studies have used skin temperature, heart rate (HR), blood pressure, and validated self-report scales to quantify the effects of interventions.^{14,18-20} Although valuable, the literature lacks controlled trials that pair self-report and physiological measures to evaluate impacts of AAT during invasive pediatric dental procedures. To address this gap, we conducted a pilot prospective controlled clinical trial to assess AAT's effects on objective (eg, salivary cortisol and α -amylase, video-coded behaviors, and HR) and subjective (eg, self-report) measures of anxiety, fear, pain, and next visit expectations. We also aimed to identify feasible outcome measures and study recommendations for future, larger randomized trials. If efficacious, AAT will offer dental care providers a noninvasive, low-risk approach to provide positive dental experiences, with the goal of reducing dental avoidance and its considerable health sequelae.

METHODS

Study design

Details of informed consent, assent, institutional review board approval (19-1911), and clinical trial registration are included in the [Appendix](#) (available online at the end of this article). Although our study is not a randomized trial, we followed the Consolidated Standards of Reporting Trials when applicable ([eTable 1](#), available online at the end of this article).²¹ Participants were recruited from the graduate pediatric dental clinic at the Adams School of Dentistry, University of North Carolina at Chapel Hill, Chapel Hill, NC; pediatric patients were scheduled semirandomly throughout the week, with no specific allocation for weekday or provider. The parents or guardians of participants (39) aged 7 through 14 years who were scheduled to receive an invasive dental procedure (ie, restoration or extraction, with or without nitrous oxide) were contacted via telephone for screening and enrollment ([eBox 1](#), available online at the end of this article, [Figure 1A](#)).

The pilot trial overview is presented in [Figure 1](#) and [eFigure 1](#), available online at the end of this article. Participants were allocated to the control group or AAT intervention group, depending on the appointment's weekday, which was determined on the basis of the therapy dog and handler's availability. On arrival, participants provided consent in a private consultation room, followed by a calming period of 7 through 9 minutes. Then, continuous video and HR recording began. Anxiety, fear, and pain assessments were completed at the visit start, in addition to collection of an unstimulated saliva sample using saliva collection Salivette swabs (Sarstedt Inc) placed into the buccal vestibule. Thereafter, the AAT intervention or control period took place for 2 minutes in the private consultation room. The AAT group interacted with the therapy dog using a reproducible, standardized method; the handler introduced the dog, asked for oral permission to approach the child, and invited participants to pet the dog, shake her paw, and give her treats. The handler and dog then left the room. Participants assigned to the control group colored a picture of a dog. At the end of the

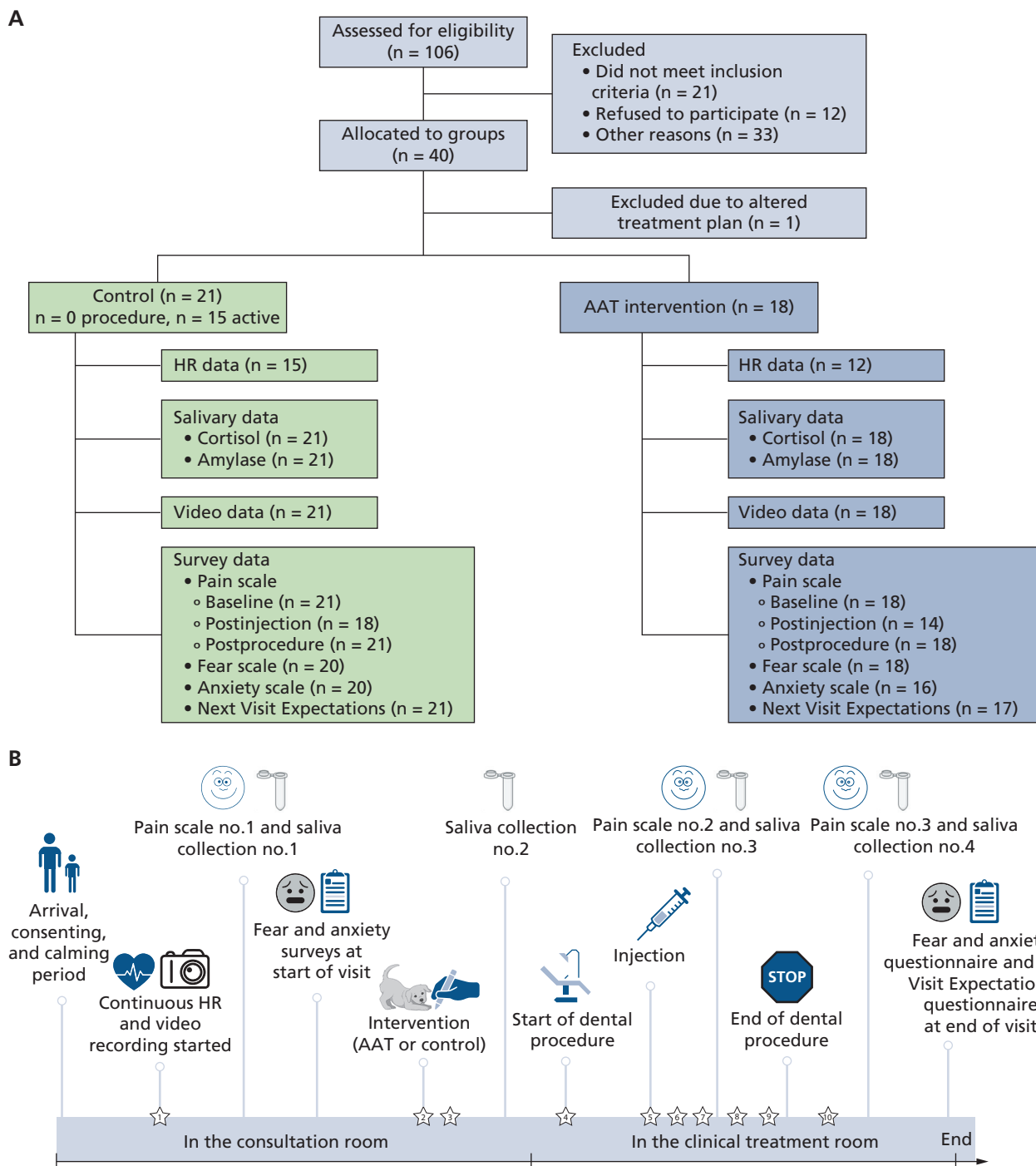


Figure 1. Trial designs and study visit summary. **A.** Consolidated Standards of Reporting Trials²¹ flowchart for enrollment and data collection. Flowchart includes the number of patients screened, enrolled, and assigned to the 2 groups (animal-assisted therapy [AAT], control). The flowchart shows patients excluded during the screening process before group assignment (66) as well as those excluded due to an altered treatment plan (1). **B.** Study visit timeline and summary. Continuous video filming with a Hero9 camera (GoPro) and heart rate (HR) recording. Baseline pain and anxiety scales and saliva (saliva collection no. 1) were obtained. Participants interacted with a therapy dog for 2 minutes (AAT group), colored a picture of a dog for 2 minutes, or sat quietly for 2 minutes. A second saliva sample was obtained 8 minutes postintervention. Participants then walked to the clinical treatment room, where the dental procedure began; 8 minutes after injection or insertion of the dental handpiece (in participants who did not receive an injection), the third saliva sample and second pain scale score were obtained. For participants receiving local anesthetic (34 [87%]), topical anesthetic was first applied, followed by injection of 2% lidocaine with 1:100,000 epinephrine. The procedure ended, and the fourth saliva sample and third pain scale score were obtained 8 minutes later, along with the fear and anxiety scale scores and Next Visit Expectations questionnaire results.

intervention, a second saliva sample was collected. The participant was then escorted into the treatment clinic for the procedure for either a restoration (ie, composite restoration, sealants, or stainless-steel crown) or extraction (Figure 1B).

Pediatric dentistry residents completed all treatments. Per clinic policy, parents or guardians were invited to be in the clinic. The procedure was attended by the patient, dental care provider, assistant, and 2 study personnel (N.G., E.N.); a parent or guardian elected to be present in 64% of visits.

The rehabilitation facility dog was a female golden retriever trained to assist in therapeutic interventions within clinical settings alongside health care professionals. Working under the guidance of a trained pediatric dentist dog handler, the rehabilitation facility dog provided support for patients with physical or neurologic disabilities, leveraging more than 2 years of specialized training to manage high-stress environments and establish rapport with multiple patients.

Physiological measurements

Measurement of Salivary Cortisol and α -Amylase

Unstimulated saliva samples were collected and processed using saliva collection Salivette swabs according to the manufacturer's instructions (SalivaBio Oral Swab, Salimetrics) at specified events and stored at -80°C until analysis (Figure 1B and eTable 2, available online at the end of this article). Salivary cortisol was quantified in duplicate using a Salivary Cortisol ELISA Kit (Salimetrics) per the manufacturer's instructions. α -Amylase activity was quantified in singles with a Salivary Alpha-Amylase Enzymatic Kit (Salimetrics). Details are provided in the Appendix.

Video Data

Video data were captured using a wireless Hero9 camera (GoPro). Videos were coded according to the paediatric dental pain, anxiety and fear coding approach,²² a software-based observational coding method, in Observer XT software (Noldus). Details are available in the Appendix.

HR

Data were collected using a Shimmer3 GSR+ unit (Shimmer Sensing) in 32 patients and a Polar Verity Sense device (Polar Electro) in 7 patients at visit start until conclusion. Details are included in the Appendix. Missing data due to technical malfunction or inability to collect data are provided in eTable 3 (available online at the end of this article); missing data points were omitted from statistical analyses.

Self-reported measures

Self-reported dental fear was measured with the Children's Fear Survey Schedule-Dental Subscale (CFSS-DS) (eBox 2, available online at the end of this article) and self-reported DA was measured using the Modified Child Dental Anxiety Scale (MCDAS) (eBox 2).^{19,23,24} The CFSS-DS was developed to assess dental fear in children; it is a revised form of the Fear Survey Schedule for Children, including dental fear items as a subset (eg, "the dentist drilling").²⁵ MCDAS has been used in children aged 8 through 15 years with reliable internal consistency and validity.²⁶ Self-reported pain was measured with the Wong-Baker FACES Pain Rating Scale (WBS).²⁷ At visit's end, participants were asked to complete the Next Visit Expectations questionnaire (eBox 3, available online at the end of this article). Details on questionnaires are available in the Appendix.

Statistical analyses

Descriptive statistics (eg, median and mean [SD]) were used for initial analysis. Anxiety (MCDAS), fear (CFSS-DS), and pain (WBS) scales, Next Visit Expectations questionnaire, and HR data were evaluated using the Mann-Whitney *U* test. Cortisol and α -amylase data were $\log_{10}$ -transformed before analysis and a Mann-Whitney *U* test was used to test for group differences. A significance threshold of $P < .05$ was used. Given the small sample size and nonnormally distributed data, nonparametric correlations (Spearman rank correlation) and group comparisons (Wilcoxon test) were performed. Analyses were performed using JMP Pro software, Version 17.2.0 (SAS Institute). Details on figure creation and statistics are provided in the Appendix.

RESULTS

Study participants

Participants (39) were well-matched across groups for sex (AAT: 61% female; control: 57% female) and age distributions (AAT: mean, 9.17 years; control: mean, 9.86 years) (Figure 1A, Table). Those

who identified as Latin American represented a majority of both groups (AAT: 72%; control: 62%). Restorations were performed in 61% of all participants (AAT: 67%, control: 57%), and extractions were performed in 36% of patients (AAT: 33%, control: 38%).

Of the 21 participants assigned to the control group, 15 colored the picture of a dog and 6 had 2 minutes of quiet time. Intraorally injected local anesthetic (2% lidocaine, 1:100,000 epinephrine after topical) was planned for all participants and administered to all except 5 participants (34 [87%] received an injection, 18 in the control group and 16 in the AAT group), due to the provider's decision to change treatments during the visit (5 [13%] did not receive an injection, 3 in the control group and 2 in the AAT group). Frankl scores were similar for control and AAT participants, indicating children had a positive to definitely positive attitude toward the dentist (Table) (control: mean, 3.7; AAT: mean, 3.8).²⁸

Effect of AAT on physiological measurements

No differences were observed between groups at any event point for salivary cortisol or α -amylase (Figures 2A and B and eTables 4 and 5, available online at the end of this article).

For every event, there was a smaller range in HR variance among the AAT group compared with the control group (Figure 2C, eFigure 2, and eTable 6, available online at the end of this article). At events immediately after movement to the clinical treatment room and between events immediately after the procedure started and 10 minutes into the procedure (Figure 2C and eFigure 2, available online at the end of this article), there was a decrease in HR observed in the AAT group that was not present in the control group.

Effect of AAT on behavioral measures of the paediatric dental pain, anxiety and fear coding approach

Participants who received AAT had a significantly longer mean duration of relaxed lower body than control participants (Figure 2D) ($P = .004$). Postprocedure CFSS-DS and MCDAS scores had significant positive correlations with the number of verbal indicators, such as crying and moaning (CFSS-DS correlation, 0.48; MCDAS correlation, 0.46; $P = .004$) (eTables 7 and 8, available online at the end of this article). Both baseline and postprocedure CFSS-DS scores were also positively correlated with MCDAS survey scores collected pre- and postprocedure. Finally, postinjection pain was significantly higher (correlation, 0.33; $P = .048$) among those who had more hand movements during the procedure.

Effect of AAT on self-reported assessments

Postprocedure, members of the control group reported significantly more pain on WBS than the AAT group ($P = .001$) (Figure 3A and eTable 4). In the control group, 53% reported increased pain postprocedure, and 21% of AAT participants reported increased pain.

Participants were asked to self-assess fear and anxiety at the start of the visit and after the dental procedure to evaluate changes across the appointment; trends were observed, although no change or group comparison was significant. When evaluating fear using CFSS-DS, 35% of the control group reported higher scores (eg, higher fear) and 56% of the AAT group reported higher scores after the procedure (not significant) (Figure 3C). Higher scores for MCDAS (eg, higher anxiety) were reported in 45% of the control group and 37% of the AAT group. The control group had a mean (SD) change in fear of -2.05 (13.29) points and a mean (SD) change in anxiety of -0.65 (6.34) points, indicating decreased fear and anxiety over the visit. The AAT group reported a mean (SD) increase of 1.577 (5.90) on the fear scale and a mean (SD) decrease of 0.195 (4.71) on the anxiety scale. There was a higher, more positive overall score on the Next Visit Expectations questionnaire among AAT participants, although this was not significant, as our sample size was likely underpowered for this measure (Figure 3B).

DISCUSSION

This pilot prospective controlled clinical trial was designed to explore the use of AAT in a pediatric dental setting. If effective, it may improve pediatric dental experiences and mitigate long-term DA and dental avoidance.²⁻⁴ However, there is a dearth of comprehensive data on how to study AAT's effects in dentistry and whether AAT is efficacious at managing dental fear, anxiety, pain, or

Table. Sample demographic characteristics.

CHARACTERISTIC	CONTROL GROUP (n = 21)	INTERVENTION (ANIMAL-ASSISTED THERAPY) GROUP (n = 18)
Age, Y		
Mean (SD)	9.86 (1.98)	9.17 (2.09)
Median	9	9
Range	7-14	7-14
Sex, No. (%)		
Female	12 (57)	11 (61)
Male	9 (43)	7 (39)
Race, No. (%)		
Black	3 (14)	3 (17)
Asian or Pacific Islander	1 (5)	0 (0)
White	4 (19)	2 (11)
Latin American	13 (62)	13 (72)
Ethnicity, No. (%)		
Hispanic	12 (57)	14 (78)
Non-Hispanic	9 (43)	4 (22)
Received an Injection, No. (%)		
Yes	18 (86)	16 (89)
No	3 (14)	2 (11)
Received Nitrous Oxide, No. (%)		
Yes	15 (71)	16 (89)
No	6 (29)	2 (11)
Type of Procedure Received, No. (%)		
Restoration	12 (57)	12 (67)
Extraction	8 (38)	6 (33)
Injection only*	1 (5)	0 (0)
Frankl Score²⁸		
Mean (SD)	3.67 (0.58)	3.78 (0.43)
Median	4.00	4.00
4, no. (%)	15 (71)	14 (78)
3, no. (%)	5 (24)	4 (22)
2, no. (%)	1 (5)	0 (0)
Pets at Home? No. (%)		
Yes	13 (62)	12 (67)
No	8 (38)	6 (33)
Anxiety Disorder? No. (%)		
Yes	3 (14)	0 (0)
No	18 (86)	18 (100)
How Afraid to Go to the Dentist? No. (%)		
Very afraid	4 (19)	0 (0)
Somewhat afraid	5 (24)	1 (6)
Only a little afraid	6 (29)	7 (39)
Not afraid at all	6 (29)	10 (56)

* One control participant received a local anesthetic injection only and no subsequent procedure due to uncooperative behavior.

Table. Continued

CHARACTERISTIC	CONTROL GROUP (n = 21)	INTERVENTION (ANIMAL-ASSISTED THERAPY) GROUP (n = 18)
Heart Rate Device Used, No. (%)		
Shimmer3 GSR+ (Shimmer Sensing)	10 (67)	10 (83)
Polar Verity Sense (Polar Electro)	5 (33)	2 (17)

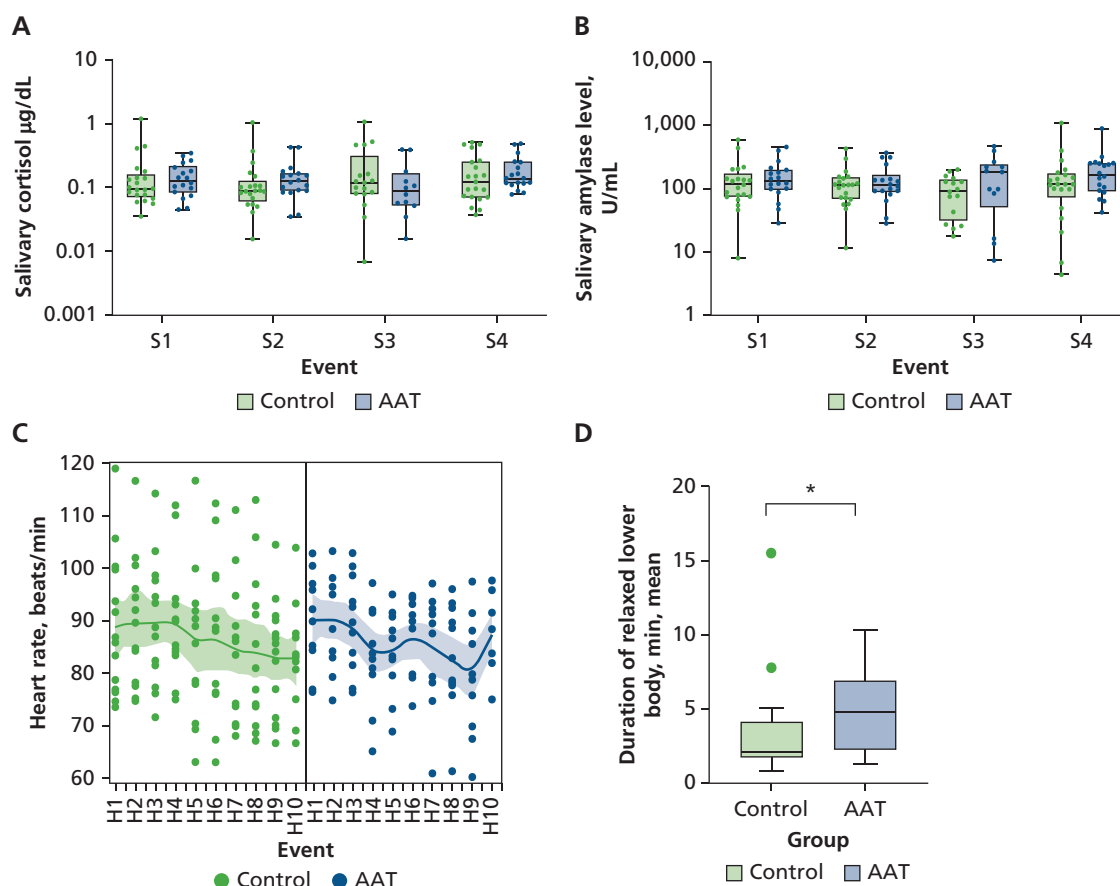


Figure 2. Physiological objective measures. **A.** Salivary cortisol levels at visit events. Each dot represents a study participant. **B.** Salivary amylase (α -amylase) levels at visit events. Each dot represents a study participant. **C.** Heart rate data with corresponding visit events. **D.** Behavioral coding results for relaxed lower body between groups. Control (green) and animal-assisted therapy (AAT) (blue) groups are displayed on the x-axis. The y-axis shows the mean duration (in minutes) of relaxed lower body during the dental procedure. Significance threshold $P < .05$. H1: After participant's calming period, but before the intervention, not concurrent with saliva collection swab placement. H2: During intervention (AAT, control). H3: Immediately after intervention (AAT, control). H4: Immediately after movement to the clinical treatment room. H5: During first injection. H6: Immediately after first injection. H7: Placement of first isolation or mouth prop. H8: Beginning procedure with handpiece or forceps into mouth. H9: During procedure (10 minutes into the procedure). H10: After procedure (removal of mouth prop, patient is seated upright). S1: Baseline at start of study visit. S2: Eight minutes after intervention (AAT or control). S3: Eight minutes into the dental procedure. S4: Eight minutes after completion of the procedure at the end of the study visit.

behavior. This pilot study was designed to begin evaluating AAT in dental settings and identify feasible outcome measures for future studies.

Stress hormones were studied in pediatric dental patients as markers of sympathetic nervous system activation via saliva, a readily available biofluid.^{29,30} Cortisol is a marker of the hypothalamic-pituitary-adrenal axis and levels peak approximately 20 through 30 minutes after onset of stress.^{29,31} Salivary cortisol was investigated in children aged 2 through 5 years with behavior management challenges undergoing dental prophylaxis.^{32,33} Salivary α -amylase was used in pediatric dental settings as a screening tool for fear.³⁴ In our study, no differences were found in these hormones, likely because collecting saliva was a new experience for patients, causing

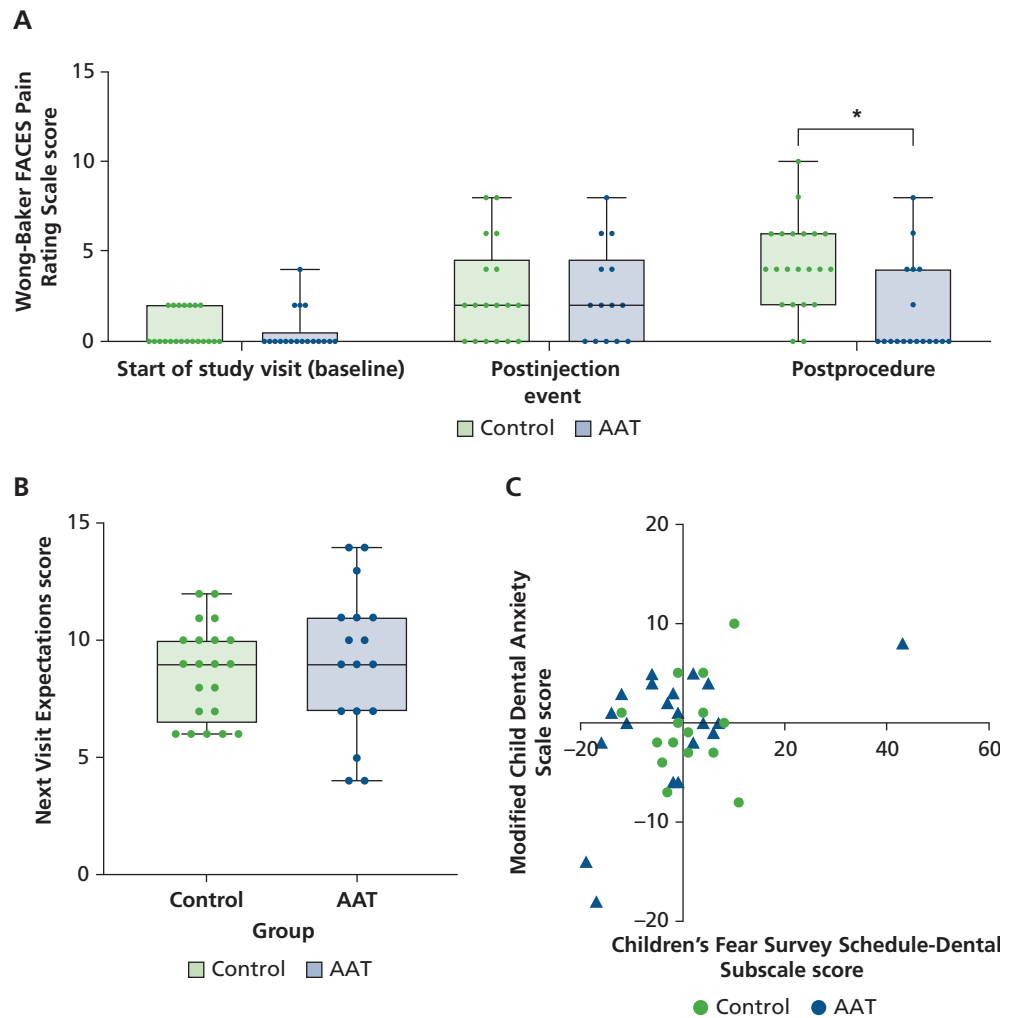


Figure 3. Survey responses. **A.** Wong-Baker FACES Pain Rating Scale²⁷ responses with corresponding events. Box plot visualization of perceptual pain scores compared between the animal-assisted therapy (AAT) (blue) and control (green) groups for each visit event. * Significant difference ($P < .05$). Each dot in the box plot represents a study participant. **B.** Next Visit Expectations questionnaire responses. A higher score indicates a more positive outlook for future visits. **C.** Anxiety scale responses. Scatter plot for both anxiety surveys (Children's Fear Survey Schedule-Dental Subscale, Modified Child Dental Anxiety Scale), each shown on a separate axis.^{25,26} Each dot presents the change in anxiety (poststudy visit score minus start of visit baseline score) for each participant. A higher, positive score indicates an increase in anxiety from the start of the study visit to the end.

sympathetic nervous system arousal, or because saliva was collected only 8 minutes after each visit event; longer wait times were not feasible in this setting. The interindividual variability of cortisol and α -amylase levels in our data set may also be attributed to their diurnal rhythms; although all appointments took place between 9 AM and 5 PM, we could not control or limit the scheduled times of dental visits.

An additional biometric measure was HR; a drop in HR immediately after movement to the clinical treatment room and after the procedure started (Figure 2C) was observed and may reflect a decrease in DA. Because anxiety is anticipatory in nature, once an anxiety-inducing event occurs (eg, going into the treatment room or starting a procedure), the HR decreases. Contrary to this, we observed a less pronounced, steady decline in HR among control participants.

DA, fear, and pain were also objectively measured using the paediatric dental pain, anxiety and fear coding approach.²² The significantly longer duration of relaxed lower body found in the AAT group (Figure 2D) may suggest a reduced response to fear and anxiety. Both the CFSS-DS and MCDAS positively correlated with verbal indicators (eg, crying or moaning and verbal responses to pain), meaning those who reported greater fear and anxiety also vocalized more frequently. The positive correlation between hand movements and postinjection pain scores indicated that participants were

more likely to put their hands over their mouth or chest when experiencing pain (eTables 7 and 8). Dental care providers can visually track these behaviors as a reflection of a patient's DA, fear, and pain.

Anxiety and fear are related but distinct states that exist on a continuum to alert people to situations perceived as threatening; anxiety prevents or prepares for future threatening situations, and fear is an in-the-moment response to manage immediate threats with an organized nervous system arousal response.³⁵⁻³⁷ Separating fear and anxiety in clinical dental settings is operationally challenging and was addressed here using a fear questionnaire and a separate anxiety questionnaire. As expected, results of these surveys showed positive but imperfect correlations, verifying that they correlate but measure distinct underlying constructs. When evaluating fear using the CFSS-DS scale, a larger percentage of the AAT group (56%) reported more fear after the procedure than the control group (35%) (Figure 3C). Higher scores were reported on the MCDAS in a larger proportion of the control group (45%) than the AAT group (37%), suggesting a larger percentage of those in the control group reported higher anxiety after the procedure. With an underpowered sample, neither trend reached significance.

Self-report scales using the WBS are validated for measuring pain in pediatric populations.²⁷ Dental pain has also been linked to anxiety.³⁸ Our findings showed that the AAT group reported significantly less pain postprocedure, suggesting that an AAT intervention may reduce postprocedure pain perceptions and DA. Although not significant, an overall higher, more positive score in the Next Visit Expectations questionnaire among AAT participants suggests a reduction in DA when anticipating future appointments. Altogether, these data suggest that AAT may reduce DA for improved oral health outcomes, although future studies are needed for definitive evidence, guided by our lessons learned (described below).

Due to its pilot nature, our study was insufficiently powered to detect small and medium effect sizes. Block randomization was not possible due to limited availability of the therapy dog handler. There were variations in dental care provider, procedure type, length, use of nitrous oxide and local anesthetic, and presence of parents or guardians in the treatment room that we could not control, as the study was designed for applicability to our pediatric practice. Variation in procedure type and use of anesthetic administration was a limitation, as a sealant is likely less anxiety-inducing for most participants than a restoration or crown involving an injection; however, all participants were scheduled to receive an invasive dental procedure requiring an injection, such that the anticipatory anxiety was likely more uniform than the ultimate procedures chosen by the dental care provider. Future studies should have more uniform procedures or large enough cohorts to allow for stratification.

Due to variable appointment times and a small sample, data could not be effectively stratified according to sex, age, or time of day; therefore, we cannot rule out impacts of diurnal hormonal variation and other confounding variables.²⁹ Similarly, our study was too underpowered to compare patients whose caregivers were present vs absent from the clinic, as their presence may influence the patients' experience; to limit the effects of the caregiver's presence, parents and guardians were asked to minimize interaction with their child during the visit. Our naturalistic study design reflects realistic pediatric settings with real-time treatment decisions; therefore, the study could not influence provider treatment decisions or caregivers' presence. We used a brief therapy dog intervention; however, longer interactions with the dog chairside throughout visits should be evaluated for efficacy. Potential effects on DA and pain perceptions were seen, even with a brief, 2-minute therapy dog intervention.

CONCLUSIONS

There was less variation in HR range among AAT participants than the control group, with decreases in HR after key events, such as procedure start, which may suggest a decrease in DA. No differences were noted in fear and anxiety scales, and salivary cortisol and α -amylase levels. The AAT group had longer durations of relaxed lower body and reported significantly less pain at the end of the procedure than the control group. Although a larger randomized controlled trial is needed to reach sufficient power, our pilot study contributes to the growing literature supporting use of AAT in dental settings and guides methodology for future investigations. AAT may be an effective adjunctive non-pharmacologic anxiety and behavioral management tool for improving the experience of pediatric dental patients in the dental office and reducing future avoidance behavior. ■

DISCLOSURE

None of the authors reported any disclosures.

SUPPLEMENTAL DATA

Supplemental data related to this article can be found at: <https://dx.doi.org/10.1016/j.adaj.2025.03.006>.

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Informed consent

Our study was carried out in accordance with the Code of Federal Regulations on the Protection of Human Subjects,^{e1} National Institutes of Health requirements for human subjects' research,^{e2} and institutional policies of the University of North Carolina Institutional Review Board and Office of Human Research Ethics (19-1911) and conforms to Consolidated Standards of Reporting Trials (CONSORT) guidelines.²¹ Data were collected as part of a registered clinical trial (ClinicalTrials.gov, registration NCT04708028). Eligible participants were enrolled after informed consent was obtained from a guardian and assent from the participant. When the study was initiated, there was a lack of published results on effect size differences for therapy dog interventions in dentistry to calculate sample size; therefore, a convenience sample of 20 participants per group was chosen and was comparable with those enrolled in similar studies.^{16,18}

Saliva collection and processing

Saliva samples were collected and processed using saliva collection Salivette swabs (Sarstedt Inc) according to manufacturer instructions (SalivaBio Oral Swab, Salimetrics). Salivette swab collections were placed in the mandibular vestibule for 2 minutes before being moved into swab storage tubes on ice (17 × 100 mm, no. 5001.05, Salimetrics). Saliva samples were collected at baseline and 8 minutes after the intervention (AAT, control) in the consultation room. Once in the clinic, a saliva sample was collected 8 minutes after the injection (n = 34). For those who did not receive an injection (n = 5), saliva was collected 8 minutes after handpiece insertion. Saliva samples were collected once more 8 minutes after the procedure ended (Figure 1B, eTable 2). Samples were centrifuged for 15 minutes at 1,500g and aliquoted before storage at -80°C.

Measurement of salivary cortisol and α -amylase

Salivary cortisol was quantified in duplicate using a Salivary Cortisol ELISA Kit (Salimetrics) per manufacturer's instructions and recommendations. Samples were not diluted on the initial run. The enzyme conjugate was diluted 1:1,600 before being added to the wells. Final samples were read at 450 nm with a 492-nm pathlength correction on a BioTek Synergy Neo 2 plate reader (Agilent Technologies). Cortisol content (reported in micrograms per deciliter) was calculated on the basis of a standard curve using Gen5.2 analysis software (Agilent Technologies). Saliva α -amylase activity was quantified in singles with a Salivary Alpha-Amylase Enzymatic Kit (Salimetrics) according to the kit's manual. Samples were diluted 1:200 and read on a BioTek Synergy Neo 2 plate reader at 405 nm at 37°C. Salivary α -amylase activity (reported in units per milliliter) was calculated using the manufacturer's formula.

Video data

Before coding, all 3 coders (R.S., E.N., O.T.) underwent identical training with our reference standard calibration video, user training guide, and detailed codebook, as described in Bocklage and colleagues.²² The calibration video is of a mock patient visit and includes examples of what would and would not be considered a code under the paediatric dental pain, anxiety and fear coding approach.²² After training and achieving a κ of greater than 0.80 on the reference standard video, coders began coding study videos. Each video was viewed in full at least twice for coding. Coders were assigned to all code every fifth video (20%) for inter-rater reliability scoring and were fair to almost perfect (mean, 0.51; range, 0.25-0.83). Interrater reliability was assessed using κ statistics in Observer XT software (Noldus).

Heart rate (HR) data

HR data were collected using a Shimmer3 GSR+ (Shimmer Sensing) in 32 patients, fitted on patients' wrists, and a Polar Verity Sense device (model 92083450; Polar Electro) in 7 patients, placed on the arm at visit start and worn until visit conclusion. Data were reviewed for inconsistencies using HR Analysis software (Mindware Technologies); the software flagged R-wave peaks on the electrocardiogram that were unclear (due to hand movements), which were then manually reviewed and removed when possible. HR data were synced to visit events using video-graphic data. The Polar device reported HR per second and the Shimmer3 reported HR per minute.

All data were standardized to beats per minute. After standardization, mean HR for 2 minutes starting with each event was quantified. As some events occurred in less than 2 minutes, the HR data corresponding to certain times capture the event and HR data after that event. Missing data due to technical malfunction or inability to collect data are described in eTable 3; missing data points and an outlier were omitted from statistical analyses.

Pain assessment

The Wong-Baker FACES Pain Rating Scale²⁷ consists of 6 faces, representing increasing levels of pain from left (no hurt, 0) to right (hurts worst, 10), scored as 0, 2, 4, 6, 8, and 10. Participants were asked to select the face that best represented their perception of pain. Patients were asked to self-assess pain at 3 points during the visit (baseline, 8 minutes after injection or 8 minutes after insertion of the handpiece in those who did not receive an injection, 8 minutes postprocedure).

Next Visit Expectations questionnaire

The Next Visit Expectations questionnaire was developed in collaboration with Jessica Grant, a survey expert at the Odum Institute for Research in Social Science, University of North Carolina, and pretested with 15 respondents (aged 4-35 years), with iterative revisions to ensure comprehension and clarity. The questionnaire consists of 4 questions to evaluate participants' excitement and anxiety regarding future dental visits. Answer choices are assigned scores from 0 through 3 or 4, with each question having its own scoring criteria.

Statistical analyses

Anxiety (Modified Child Dental Anxiety Scale²⁶) and fear (Children's Fear Survey Schedule-Dental Subscale²⁵) measures were expressed as the percentage of participants who reported increased anxiety and fear from baseline (ie, visit start) to procedure end (ie, visit end) and mean change in fear and anxiety from the beginning of the visit to the end, with standard deviations reported. Anxiety (Modified Child Dental Anxiety Scale), fear (Children's Fear Survey Schedule-Dental Subscale), pain scales (Wong-Baker FACES Pain Rating Scale²⁷), Next Visit Expectations questionnaire, and HR data were evaluated using the Mann-Whitney *U* test to compare groups. Statistical analyses were performed with Prism software (GraphPad). Behavioral and self-report variables, analyzed through the paediatric dental pain, anxiety and fear coding approach,²² were assessed descriptively and for outliers. On the basis of outlier analyses, 2 observations were excluded from further video analysis, leaving a final sample of 37 participants (20 control, 17 AAT). Data from the full sample are reported in eFigure 2, consistent with intention-to-treat analysis.

Figures were created using Prism (Figure 2, Figure 3, eFigure 2), BioRender (Figure 1, eFigure 1), and Illustrator (Adobe) (Figure 2, Figure 3, eFigure 2). Descriptive, correlational, and comparative analyses were performed using JMP Pro, Version 17.2.0 (SAS Institute).

Study design recommendations and feasibility

Because sex, stage of puberty, weight, and time of day can influence salivary cortisol, future studies should schedule visits within a consistent, limited timeframe to minimize diurnal hormone fluctuations, with stratification according to sex, age, and weight.³²

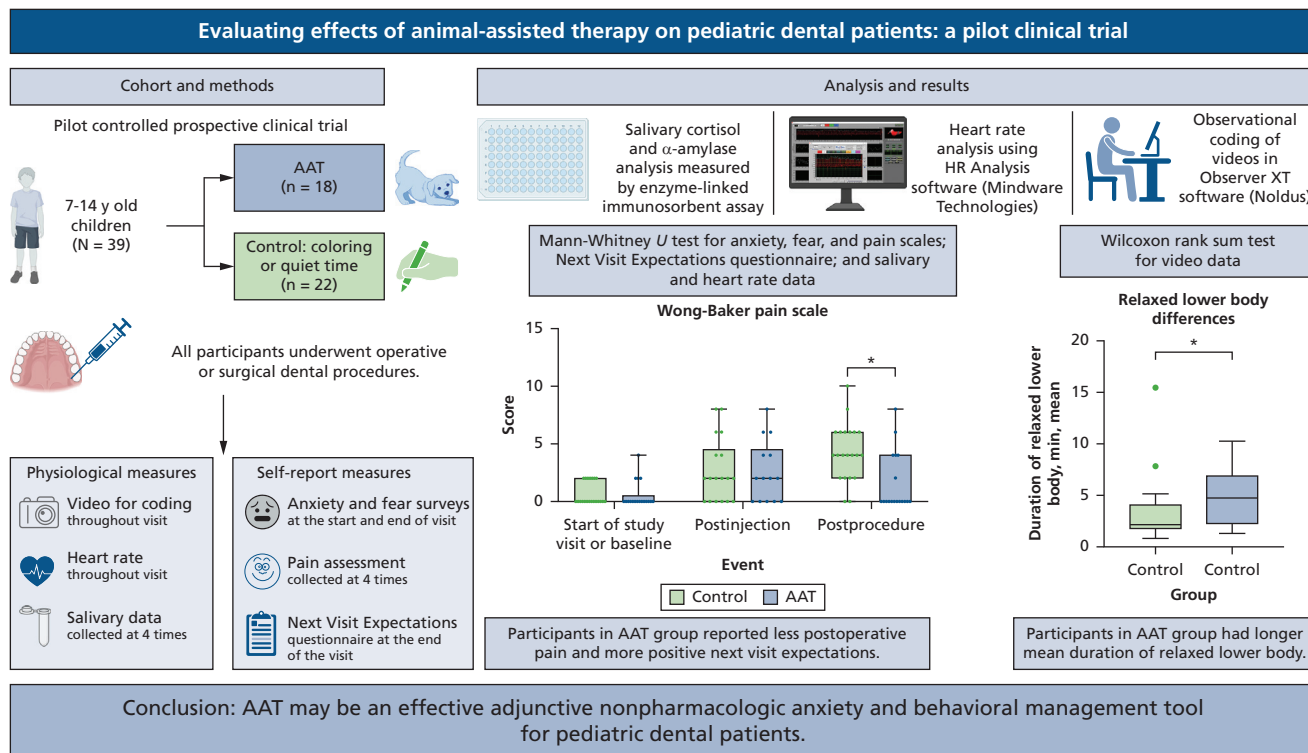
We encountered technical issues with the HR and galvanic skin response (GSR) measurements using a hand or wrist-worn Shimmer3 GSR+ device. GSR quantifies emotional arousal via skin conductance due to sweating; our GSR data were largely unusable due to inconsistencies and frequent malfunctions during patients' arm movements. The Shimmer3 GSR+ device is only operational when users keep their movements to a minimum, which is poorly suited for pediatrics.^{e3} In addition, HR data obtained from the Shimmer3 GSR+ device require manual cleanup, which takes from 1 through 3 hours per video. In contrast, the Polar Verity Sense yielded consistent HR data that could be exported directly to a spreadsheet, streamlining analysis. Therefore, we recommend using the Polar device for monitoring HR, and either forgoing or testing a different hand-, wrist-, or chest-worn GSR device that is minimally sensitive to movement. Syncing data across multiple data sets (eg, video and HR) also requires careful planning to match event timestamps to save analysis time. Video coding using the paediatric dental pain, anxiety and fear coding approach²² was feasible and informative, although time-intensive, requiring roughly 3 times the

duration of a video for coding. Ensuring greater consistency in dental procedures would limit variability in video length.

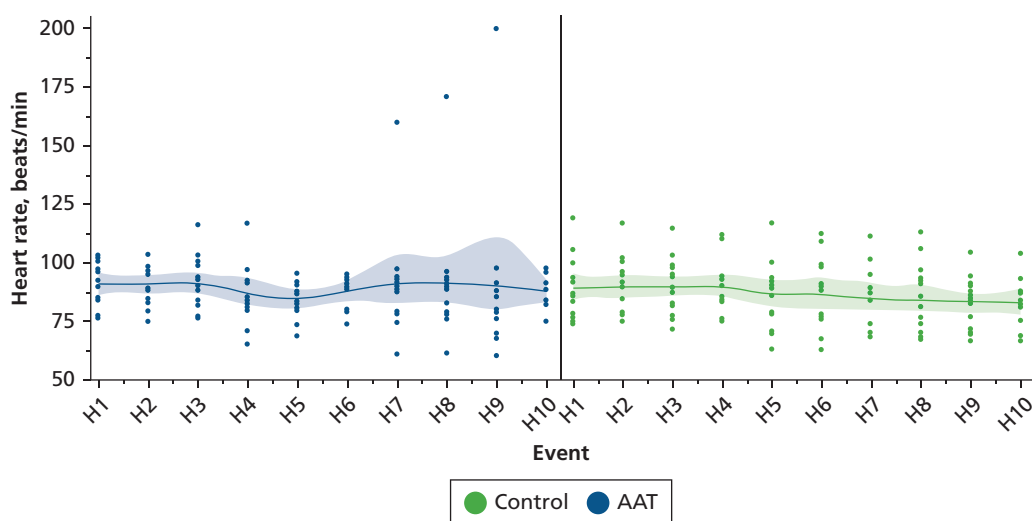
SUPPLEMENTAL RESULTS

There were no significant differences between active and passive controls for outcome measures (data not shown).

- e1. 45 CFR 46. Office of Human Research Protections, US Department of Health and Human Services. Accessed March 29, 2025. <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>
- e2. Human subjects research. National Institutes of Health. Accessed March 29, 2025. <https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects>
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eFigure 1. Evaluating the effects of animal-assisted therapy (AAT) on pediatric dental patients. * Significant difference ($P < .05$).



eFigure 2. Heart rate data for all participants, including outliers. H1: After participant's calming period, but before intervention, not concurrent with saliva collection Salivette swab (Sarstedt Inc) placement. H2: During intervention (animal-assisted therapy [AAT], control). H3: Immediately after intervention (AAT, control). H4: Immediately after movement to the clinical treatment room. H5: During first injection. H6: Immediately after first injection. H7: Placement of first isolation or mouth prop. H8: Beginning procedure with handpiece or forceps into mouth. H9: During procedure (10 minutes into the procedure). H10: After procedure (removal of mouth prop, patient is seated upright).

eTable 1. CONSORT^{*,21} 2010 checklist of information to include when reporting a randomized trial.[†]

ARTICLE ELEMENT	ITEM NO.	CHECKLIST ITEM	PAGE NO.
Title and Abstract			
	1a	Identification as a randomized trial in the title	NA ^{‡,§}
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	447
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	448
	2b	Specific objectives or hypotheses	448
Methods			
Trial design	3a	Description of trial design (eg, parallel or factorial) including allocation ratio	448
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	448
Participants	4a	Eligibility criteria for participants	eBox 1
	4b	Settings and locations where the data were collected	448
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	448-450
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	450
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	Appendix
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomization			448, 455
Sequence generation	8a	Method used to generate the random allocation sequence	448
	8b	Type of randomization; details of any restriction (such as blocking and block size)	448, 455, NA [§]
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA [§]
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	450
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	450, Appendix
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	448, 449, Figure 1A
	13b	For each group, losses and exclusions after randomization, together with reasons	Figure 1A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Appendix
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	eTable 4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% CI)	451, eTables 4 and 5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	454, 455

* CONSORT: Consolidated Standards of Reporting Trials. † We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for clarification on the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials, noninferiority and equivalence trials, nonpharmacologic treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org. ‡ NA: Not applicable. § Block randomization was not possible in this naturalistic clinical setting due to the handler and therapy dog's limited availability. The handler and therapy dog were only available certain days each week. Pediatric patients were assigned to either experimental (animal-assisted therapy) or control groups on the basis of the day of their scheduled visit. Patients were scheduled throughout the week, without being assigned to a particular provider.

eTable 1. Continued

ARTICLE ELEMENT	ITEM NO.	CHECKLIST ITEM	PAGE NO.
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	455, 457.e2
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	454, 455, 457.e2
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	454, 455
Other information			
Registration	23	Registration number and name of trial registry	457.e1
Protocol	24	Where the full trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	456

eTable 2. Events for salivary and heart rate data collection.

EVENT	DESCRIPTION
Salivary Data Collection	
S1	Baseline (preintervention, in consultation room)
S2	Postintervention (8 min after intervention)
S3	8 min into the dental procedure
S4	8 min after completion of the procedure at the end of the study visit
Heart Rate Data Collection	
H1	After calming period, but before intervention; not concurrent with saliva collection swab Salivette (Sarstedt Inc) placement
H2	During intervention (animal-assisted therapy, control)
H3	Immediately after intervention (animal-assisted therapy, control)
H4	Immediately after movement to clinical treatment room
H5	During first injection
H6	Immediately after first injection (needle has left the mouth)
H7	Placement of first isolation or mouth prop
H8	Beginning procedure with handpiece or forceps into mouth
H9	During procedure (10 min into procedure)
H10	After procedure (removal of mouth prop, patient is seated upright)

eTable 3. Missing data.

PARTICIPANT NO.	HEART RATE	CORTISOL AND AMYLASE, SALIVA SAMPLE NO.				WONG-BAKER FACES PAIN RATING SCALE ²⁷		
		1	2	3	4	Start of Study Visit	Postinjection	Postprocedure*
1	I [†]	C, [‡] A [§]	C, A	C, A	C, A	+ [¶]	+	+
2	F [#]	C, A	C, A	–, ** A	C, A	+	+	+
3	M ^{††}	C, A	C, A	C, A	C, A	+	+	+
4	I	C, A	C, A	–, –	C, A	+	–	+
5	F	C, A	C, A	C, A	C, A	+	+	+
6	I	C, A	C, A	C, A	C, A	+	+	+
7	F	C, A	C, A	C, A	C, A	+	+	+
8	M	C, A	C, A	C, A	C, A	+	+	+
9	F	C, A	C, A	–, –	C, A	+	+	+
10	I	C, A	C, A	C, A	C, A	+	–	+
11	M	C, A	C, A	C, A	C, A	+	+	+
12	I	C, A	C, A	C, A	C, A	+	+	+
13	F	C, A	C, A	C, A	C, A	+	+	+
14	I	C, A	C, A	C, A	C, A	+	+	+
16	M	C, A	C, A	C, A	C, A	+	+	+
17	M	C, A	C, A	C, A	C, A	+	+	+
18	M	C, A	C, A	C, A	C, A	+	+	+
19	M	C, A	C, A	C, A	C, A	+	+	+
20	F	C, A	C, A	–, –	C, A	+	–	+
21	I	C, A	C, A	C, A	C, A	+	+	+
22	I	C, A	C, A	–, –	C, A	+	+	+
23	I	C, A	C, A	C, A	C, A	+	+	+
24	I	C, A	C, A	C, A	C, A	+	+	+
25	M	C, A	C, A	–, –	C, A	+	+	+
26	M	C, A	C, A	–, –	C, A	+	+	+
27	F	C, A	C, A	C, A	C, A	+	+	+
28	M	C, A	C, A	C, A	C, A	+	–	+
29	I	C, A	C, A	–, –	C, A	+	–	+
30	M	C, A	C, A	C, A	C, A	+	+	+
31	F	C, A	C, A	C, A	C, A	+	+	+
32	I	C, A	C, A	–, –	C, A	+	–	+
33	F	C, A	C, A	C, A	C, A	+	+	+
34	I	C, A	C, A	C, A	C, A	+	+	+
35	I	C, A	C, A	C, A	C, A	+	+	+
36	M	C, A	C, A	C, A	C, A	+	+	+
37	F	C, A	C, A	–, –	C, A	+	+	+
38	F	C, A	C, A	C, A	C, A	+	+	+
39	I	C, A	C, A	C, A	C, A	+	+	+
40	F	C, A	C, A	C, –	C, A	+	–	+

*. Postprocedure: End of the study visit. †. I: Incomplete data set (missing 1 or more data points). ‡. C: Cortisol data are available. §. A: Amylase data are available.
¶. +: Available data. #. F: Full data set (all data points were recorded for all events). **. –: Missing data. ††. M: Missing data set (missing all data points).

eTable 3. (Continued)

[illegible]

eTable 4. Biological objective data for AAT* and control groups.

EVENT	AAT GROUP (n = 18)			TOTAL CONTROL GROUP (n = 21)			P VALUE
	Mean (SD)	Median	95% CI for Mean	Mean (SD)	Median	95% CI for Mean	
Amylase Level [†]							
S1	166.70 (114.32)	133.95	113.89 to 219.51	150.82 (135.01)	118.10	93.08 to 208.56	.379
S2	145.39 (99.02)	116.16	99.65 to 191.13	127.77 (92.46)	116.20	88.22 to 167.32	.646
S3	175.11 (144.37)	186.99	108.42 to 241.80	97.78 (59.65)	94.95	72.27 to 123.29	.219
S4	210.05 (188.93)	169.95	122.77 to 297.33	175.10 (232.24)	120.20	75.55 to 274.43	.223
Cortisol Level [†]							
S1	0.155 (0.090)	0.130	0.11 to 0.20	0.185 (0.255)	0.097	0.08 to 0.29	.410
S2	0.154 (0.112)	0.128	0.10 to 0.21	0.153 (0.219)	0.090	0.06 to 0.25	.127
S3	0.133 (0.090)	0.129	0.09 to 0.17	0.223 (0.273)	0.119	0.11 to 0.34	.268
S4	0.193 (0.127)	0.140	0.13 to 0.25	0.186 (0.157)	0.126	0.12 to 0.25	.353
Heart Rate [‡]							
H1	90.99 (9.30)	90.02	86.69 to 95.29	88.76 (12.99)	85.90	83.20 to 94.32	.643
H2	89.84 (9.36)	91.70	85.52 to 94.16	89.65 (12.37)	89.51	84.36 to 94.94	.784
H3	89.41 (9.12)	89.48	85.20 to 93.62	89.12 (11.86)	87.79	84.05 to 94.19	.851
H4	83.71 (9.54)	83.85	80.30 to 89.12	90.07 (11.05)	89.83	85.34 to 94.80	.228
H5	83.87 (8.25)	84.88	80.06 to 87.68	85.44 (14.85)	87.34	79.09 to 91.79	.872
H6	87.46 (7.32)	90.24	84.08 to 90.84	87.12 (15.63)	88.32	80.44 to 93.80	.771
H7	84.38 (11.07)	88.54	79.27 to 89.49	84.03 (13.63)	84.82	78.20 to 89.86	.582
H8	83.07 (10.17)	82.73	78.37 to 87.77	84.05 (14.20)	80.88	77.98 to 90.12	.851
H9	79.37 (11.55)	79.19	74.03 to 84.71	82.83 (10.84)	84.79	78.19 to 87.47	.546
H10	88.49 (7.15)	91.35	86.19 to 91.79	82.82 (10.09)	82.90	78.50 to 87.14	.115
Wong-Baker FACES Pain Rating Scale ²⁷							
Start of study visit or baseline	0.56 (1.15)	0	0.01 to 1.09	0.67 (0.97)	0	0.260 to 1.08	.620
Postinjection [§]	2.57 (2.65)	2	1.35 to 3.79	2.71 (2.82)	2	1.50 to 3.92	.950
Postprocedure [¶]	1.56 (2.53)	0	0.39 to 2.73	4.29 (2.47)	4	3.23 to 5.35	.001 [#]
Fear Scale (Children's Fear Survey Schedule-Dental Subscale ²⁵)							
Start of study visit or baseline	31.22 (13.25)	26.00	25.10 to 37.34	37.40 (12.08)	39.50	32.23 to 42.57	.097
Postprocedure	32.78 (13.43)	32.00	26.58 to 38.98	35.05 (12.67)	35.00	29.63 to 40.47	.582
Change	1.56 (5.90)	1.00	−1.17 to 4.29	−2.05 (13.29)	−2.00	−7.73 to 3.63	.075
Anxiety Scale (Modified Child Dental Anxiety Scale ²⁶)							
Start of study visit or baseline	18.13 (5.48)	17.00	15.60 to 20.66	21.05 (5.84)	19.50	18.55 to 23.55	.137
Postprocedure	18.61 (9.15)	17.50	14.38 to 22.84	20.40 (7.41)	19.50	17.23 to 23.57	.365
Change	−0.19 (4.71)	−0.50	−2.37 to 1.99	−0.65 (6.34)	0.50	−3.36 to 2.06	.653
Next Visit Expectations Questionnaire							
Postprocedure	9.12 (3.14)	9	7.67 to 10.57	8.67 (2.03)	9	7.80 to 9.54	.573

* AAT: Animal-assisted therapy. † S1: Baseline at start of study visit. S2: 8 minutes after intervention (AAT, control). S3: 8 minutes into the dental procedure. S4: 8 minutes after completion of the procedure at the end of the study visit. ‡ H1: After calming period, but before intervention; not concurrent with saliva collection swab placement. H2: During intervention (AAT, control). H3: Immediately after intervention (AAT, control). H4: Immediately after movement to clinical treatment room. H5: During first injection. H6: Immediately after first injection (needle has left the mouth). H7: Placement of first isolation or mouth prop. H8: Beginning procedure with handpiece or forceps into mouth. H9: During procedure (10 minutes into procedure). H10: After procedure (removal of mouth prop, patient is seated upright). § For those who did not receive an injection, data were recorded after the insertion of the dental handpiece. ¶ Postprocedure: End of study visit. # Significance level $P < .05$, results from Mann-Whitney U test.

eTable 5. Biological objective data for control groups.

EVENT	PASSIVE CONTROL (n = 6)			ACTIVE CONTROL (n = 15)			P VALUE
	Mean (SD)	Median	95% CI for Mean	Mean (SD)	Median	95% CI for Mean	
Amylase Level*							
S1	174.23 (139.02)	125.60	62.99 to 285.47	141.46 (137.15)	104.76	72.05 to 210.87	.733
S2	138.57 (86.10)	116.25	69.68 to 207.46	123.45 (97.44)	116.20	74.14 to 172.76	.677
S3	106.58 (55.17)	107.85	62.44 to 150.72	92.50 (64.47)	88.95	59.87 to 125.13	.793
S4	318.40 (406.52)	128.95	−6.88 to 643.68	117.78 (75.56)	120.20	79.54 to 156.02	.470
Cortisol Level*							
S1	0.168 (0.129)	0.113	0.06 to 0.27	0.192 (0.295)	0.097	0.04 to 0.34	.519
S2	0.160 (0.111)	0.122	0.07 to 0.25	0.151 (0.253)	0.088	0.02 to 0.28	.184
S3	0.189 (0.169)	0.129	0.05 to 0.32	0.242 (0.323)	0.098	0.08 to 0.41	.404
S4	0.253 (0.181)	0.180	0.11 to 0.40	0.160 (0.144)	0.095	0.09 to 0.23	.178
Heart Rate†							
H1	78.78 (6.38)	76.85	73.68 to 83.88	91.26 (13.17)	89.18	84.60 to 97.92	.136
H2	79.17 (4.59)	78.16	75.50 to 82.84	92.79 (12.32)	93.19	86.56 to 99.02	.112
H3	81.52 (5.41)	81.44	77.19 to 85.85	91.19 (12.44)	93.43	84.89 to 97.49	.170
H4	80.21 (7.33)	80.21	74.34 to 86.08	91.87 (10.87)	90.28	86.37 to 97.37	.231
H5	80.53 (16.00)	80.53	67.73 to 93.33	86.43 (15.32)	87.34	78.68 to 94.18	.758
H6	82.93 (22.12)	82.93	65.23 to 100.63	87.95 (15.48)	88.32	80.12 to 95.78	.909
H7	71.95 (3.02)	71.95	69.53 to 74.37	86.41 (14.51)	86.23	79.07 to 93.75	.273
H8	79.82 (11.76)	76.87	70.41 to 89.23	85.20 (15.09)	80.91	77.56 to 92.84	.769
H9	85.53 (8.57)	85.54	78.67 to 92.39	82.09 (11.63)	84.03	76.20 to 87.98	.659
H10	89.36 (12.70)	83.61	79.20 to 99.52	80.64 (8.85)	82.74	76.16 to 85.12	.482
Wong-Baker FACES Pain Rating Scale ²⁷							
Start of study visit or baseline	0.33 (0.82)	0	−0.33 to 0.99	0.80 (1.01)	0	0.29 to 1.31	.613
Postinjection‡	4.80 (2.28)	4	2.98 to 6.62	1.85 (2.51)	2	0.58 to 3.12	.026 [§]
Postprocedure [¶]	5.33 (1.63)	5	4.03 to 6.63	3.87 (2.67)	4	2.52 to 5.22	.189
Fear Scale (Children’s Fear Survey Schedule-Dental Subscale ²⁵)							
Start of study visit or baseline	31.83 (9.83)	36.00	23.96 to 39.70	39.79 (12.48)	41.50	33.47 to 46.11	.105
Postprocedure	31.83 (9.35)	36.00	24.35 to 39.31	36.33 (13.85)	34.00	29.32 to 43.34	.806
Change	0.00 (3.85)	0.50	−3.08 to 3.08	−2.93 (15.80)	−4.50	−10.93 to 5.07	.283
Anxiety Scale (Modified Child Dental Anxiety Scale ²⁶)							
Start of study visit or baseline	18.67 (6.65)	19.00	13.35 to 23.99	22.07 (5.38)	21.00	19.35 to 24.79	.404
Postprocedure	20.17 (7.08)	23.00	14.50 to 25.84	20.50 (7.43)	18.00	16.74 to 24.26	.952
Change	1.50 (4.51)	3.50	−2.11 to 5.11	−1.57 (6.91)	0.00	−5.07 to 1.93	.266
Next Visit Expectations Questionnaire							
Postprocedure	7.33 (1.21)	7.5	6.36 to 8.30	9.20 (2.08)	10	8.15 to 10.25	.049 [§]

* S1: Baseline at start of study visit. S2: 8 minutes after intervention (animal-assisted therapy [AAT], control). S3: 8 minutes into the dental procedure. S4: 8 minutes after completion of the procedure at the end of the study visit. † H1: After calming period, but before intervention; not concurrent with saliva collection swab placement. H2: During intervention (AAT, control). H3: Immediately after intervention (AAT, control). H4: Immediately after movement to clinical treatment room. H5: During first injection. H6: Immediately after first injection (needle has left the mouth). H7: Placement of first isolation or mouth prop. H8: Beginning procedure with handpiece or forceps into mouth. H9: During procedure (10 minutes into procedure). H10: After procedure (removal of mouth prop, patient is seated upright). ‡ For those who did not receive an injection, data were recorded after insertion of the dental handpiece. § Significance level $P < .05$, results from Mann-Whitney U test. ¶ Postprocedure: End of study visit.

eTable 6. Heart rate variance for AAT* and control groups at each event point.

HEART RATE EVENT [†]	AAT GROUP (n = 18)	TOTAL CONTROL GROUP (n = 21)
H1	86.42	173.32
H2	87.67	151.79
H3	83.13	154.83
H4	90.99	118.26
H5	68.09	234.77
H6	53.55	239.57
H7	122.51	187.24
H8	103.46	227.69
H9	133.50	135.16
H10	51.16	78.24

* AAT: Animal-assisted therapy. † H1: After calming period, but before intervention; not concurrent with saliva collection swab placement. H2: During intervention (AAT, control). H3: Immediately after intervention (AAT, control). H4: Immediately after movement to clinical treatment room. H5: During first injection. H6: Immediately after first injection (needle has left the mouth). H7: Placement of first isolation or mouth prop. H8: Beginning procedure with handpiece or forceps into mouth. H9: During procedure (10 minutes into procedure). H10: After procedure (removal of mouth prop, patient is seated upright).

eTable 7. Multivariate correlations between self-reported measures and behavioral data.

SELF-REPORTED MEASURE	BEHAVIOR	COEFFICIENT	P VALUE
Postprocedure Fear Scale	Total number of verbal indicators (crying or moaning, verbal response to pain, heavy audible breathing, asking questions about procedure)	0.4775	.0028*
Postprocedure Anxiety Scale	Total number of verbal indicators (crying or moaning, verbal response to pain, heavy audible breathing, asking questions about procedure)	0.4634	.0039*
Baseline Pain Scale	Total number of gaze indicators (looking around the room, looking at the dental equipment)	−0.2822	.0906 [†]
Baseline Pain Scale	Total number of eye movements (rapid or repetitive blinking, wincing, looking around the room, looking at the dental equipment)	−0.3033	.068 [†]
Postinjection Pain Scale	Total number of hand movements (hands over the chest, holding up hands, hands over the mouth)	0.328	.0475*
Postprocedure Pain Scale	Total number of gaze indicators (looking around the room, looking at the dental equipment)	−0.4609	.0041*
Postprocedure Pain Scale	Total number of eye movements (rapid or repetitive blinking, wincing, looking around the room, looking at the dental equipment)	−0.4969	.0018*

* Significance level $P < .05$. † Borderline significance level $P < .01$.

eTable 8. Multivariate correlations between self-reported measure data.

SELF-REPORTED MEASURE	SELF-REPORTED MEASURE	COEFFICIENT	P VALUE
Baseline Fear Scale	Baseline anxiety scale	0.5317	.0007*
Baseline Fear Scale	Postprocedure fear scale	0.6561	< .0001*
Baseline Fear Scale	Postprocedure anxiety scale	0.6012	< .0001*
Baseline Fear Scale	Baseline pain scale	0.2984	.0728 [†]
Baseline Fear Scale	Postprocedure pain scale	0.2912	.0804 [†]
Baseline Anxiety Scale	Baseline pain scale	0.3775	.0213*
Baseline Anxiety Scale	Postprocedure fear scale	0.4484	.0054*
Baseline Anxiety Scale	Postprocedure anxiety scale	0.3692	.0245*
Baseline Anxiety Scale	Postprocedure pain scale	0.3854	.0185*
Baseline Pain Scale	Postprocedure pain scale	0.3855	.0184*
Postprocedure Fear Scale	Postprocedure anxiety scale	0.8316	< .0001*

* Significance level $P < .05$. [†] Borderline significance level $P < .01$.

eBox 1. Enrollment criteria.

INCLUSION CRITERIA

- People with stable physical health (American Society of Anesthesiologists Physical Status Classifications^{e4} I and II), decided at the discretion of the study coordinators (N.G., E.N.)
- Aged 4 through 17 years
- Had a prior dental visit at the graduate pediatric dental clinic, University of North Carolina
- Previous Frankl Behavior Scale²⁸ score of 2, 3, or 4.
- Planned procedure included an injection
- Able to comprehend and follow the requirements of the study (including availability on scheduled visit dates) on the basis of the assessment of research site personnel

EXCLUSION CRITERIA

- Previous traumatic experience with a dog or fear of dogs
- Allergy to dogs or oral hygiene products (toothpaste, mouthrinse)
- Xerostomia
- Craniofacial abnormalities that complicate dental treatment
- Significant learning disability or a developmental delay, at the discretion of the study team
- Complex medical history that complicates dental treatment, at the discretion of the study team
- Patient unwilling to assent or participate or parent or guardian consent was not given

eBox 2. Validated fear and anxiety questionnaires.

QUESTIONNAIRE

Children's Fear Survey Schedule - Dental Subscale²⁵

How afraid are you of . . .

1. Dentists
2. Doctors
3. Injections
4. Having somebody examine your mouth
5. Having to open your mouth
6. Having a stranger touch you
7. Having somebody look at you
8. The dentist drilling
9. The sight of the dentist drilling
10. The noise of the dentist drilling
11. Having somebody put instruments in your mouth
12. Choking
13. Having to go to hospitals
14. People in white uniforms
15. Having the nurse clean your teeth

Modified Child Dental Anxiety Scale²⁶

How do you feel about...

1. Going to the dentist in general
2. Having your teeth looked at
3. Having your teeth scraped and polished
4. Having an injection in the gums
5. Having a filling
6. Having a tooth taken out
7. Being put to sleep to have a treatment
8. Having a mixture of gas and air, which will help you to feel comfortable for treatment but cannot put you to sleep

ANSWER CHOICES AND ASSIGNED SCORES

Not afraid at all (+1)
A little afraid (+2)
A fair amount afraid (+3)
Pretty much afraid (+4)
Very afraid (+5)

Relaxed or not worried (+1)
Very slightly worried (+2)
Fairly worried (+3)
Worried a lot (+4)
Very worried (+5)

eBox 3. Next Visit Expectations questionnaire.

QUESTION

1. How excited are you to go to the dentist for a future visit?
2. Did your experience today change how excited you are to visit the dentist in the future? Did it make you . . .
3. How afraid are you to go to the dentist for a future visit?
4. Did your experience today change how afraid you are to visit the dentist in the future? Did it make you . . .

ANSWER CHOICES AND ASSIGNED SCORES

Very excited (+3)
Somewhat excited (+2)
Only a little excited (+1)
Not at all excited (0)
Much more excited (+4)
A little more excited (+3)
No change in excitement (+2)
A little less excited (+1)
Much less excited (0)
Very afraid (0)
Somewhat afraid (+1)
Only a little afraid (+2)
Not at all afraid (+3)
A lot more afraid (0)
A little more afraid (+1)
No change in fear (+2)
A little less afraid (+3)
Much less afraid (+4)